

AMENDED IN SENATE JULY 1, 2005

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN SENATE JUNE 6, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

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**ASSEMBLY BILL**

**No. 522**

**Introduced by Assembly Members Plescia and Bogh**  
*(Principal coauthor: Senator Alquist)*  
**(Coauthors: Assembly Members Spitzer and Vargas)**

February 16, 2005

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An act to amend Section 1261.6 of the Health and Safety Code, to add Section 290.02 to the Penal Code, and to add Section 14133.225 to the Welfare and Institutions Code, relating to prescription drugs and other therapies, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 522, as amended, Plescia. Automated drug delivery system: Medi-Cal coverage: drugs or other therapies: registered sex offenders.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further

clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care services, pursuant to a schedule of health care benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid provisions.

Existing law requires a person who has committed one or more designated sex crimes to register with the law enforcement agency of the city, county, city and county, or campus in which the person resides. Existing law provides that the Department of Justice shall make available information concerning specified registered sex offenders to the public via an Internet Web site.

This bill would provide that the State Department of Health Services shall not provide or pay for any prescription drug or therapy to treat erectile dysfunction for any Medi-Cal recipient required to register pursuant to these provisions, except to the extent it is required under federal law.

This bill would require the Department of Justice to ~~provide, upon written request, identify the names and relevant information pertaining to~~ of persons required to register under these provisions *from a list of persons provided by the requesting agency, and provide those names and other information necessary to verify proper identification*, to any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of these persons.

This bill would authorize the Department of Justice to establish a fee for the above requests.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote:  $\frac{2}{3}$ . Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 1261.6 of the Health and Safety Code is
- 2 amended to read:
- 3 1261.6. (a) (1) For purposes of this section and Section
- 4 1261.5, an “automated drug delivery system” means a
- 5 mechanical system that performs operations or activities, other

1 than compounding or administration, relative to the storage,  
2 dispensing, or distribution of drugs. An automated drug delivery  
3 system shall collect, control, and maintain all transaction  
4 information to accurately track the movement of drugs into and  
5 out of the system for security, accuracy, and accountability.

6 (2) For purposes of this section, “facility” means a health  
7 facility licensed pursuant to subdivision (c), (d), or both, of  
8 Section 1250 that has an automated drug delivery system  
9 provided by a pharmacy.

10 (3) For purposes of this section, “pharmacy services” means  
11 the provision of both routine and emergency drugs and  
12 biologicals to meet the needs of the patient as prescribed by a  
13 physician.

14 (b) Transaction information shall be made readily available in  
15 a written format for review and inspection by individuals  
16 authorized by law. These records shall be maintained in the  
17 facility for a minimum of three years.

18 (c) Individualized and specific access to automated drug  
19 delivery systems shall be limited to facility and contract  
20 personnel authorized by law to administer drugs.

21 (d) (1) The facility and the pharmacy shall develop and  
22 implement written policies and procedures to ensure safety,  
23 accuracy, accountability, security, patient confidentiality, and  
24 maintenance of the quality, potency, and purity of stored drugs.  
25 Policies and procedures shall define access to the automated drug  
26 delivery system and limits to access to equipment and drugs.

27 (2) All policies and procedures shall be maintained at the  
28 pharmacy operating the automated drug delivery system and the  
29 location where the automated drug delivery system is being used.

30 (e) When used as an emergency pharmaceutical supplies  
31 container, drugs removed from the automated drug delivery  
32 system shall be limited to the following:

33 (1) A new drug order given by a prescriber for a patient of the  
34 facility for administration prior to the next scheduled delivery  
35 from the pharmacy, or 72 hours, whichever is less. The drugs  
36 shall be retrieved only upon authorization by a pharmacist and  
37 after the pharmacist has reviewed the prescriber’s order and the  
38 patient’s profile for potential contraindications and adverse drug  
39 reactions.

1 (2) Drugs that a prescriber has ordered for a patient on an  
2 as-needed basis, if the utilization and retrieval of those drugs are  
3 subject to ongoing review by a pharmacist.

4 (3) Drugs designed by the patient care policy committee or  
5 pharmaceutical service committee of the facility as emergency  
6 drugs or acute onset drugs. These drugs may be retrieved from an  
7 automated drug delivery system pursuant to the order of a  
8 prescriber for emergency or immediate administration to a  
9 patient of the facility. Within 48 hours after retrieval under this  
10 paragraph, the case shall be reviewed by a pharmacist.

11 (f) When used to provide pharmacy services pursuant to  
12 Section 4119.1 of the Business and Professions Code, the  
13 automated drug delivery system shall be subject to all of the  
14 following requirements:

15 (1) Drugs removed from the automated drug delivery system  
16 for administration to a patient shall be in properly labeled units of  
17 administration containers or packages.

18 (2) A pharmacist shall review and approve all orders prior to a  
19 drug being removed from the automated drug delivery system for  
20 administration to a patient. The pharmacist shall review the  
21 prescriber's order and the patient's profile for potential  
22 contraindications and adverse drug reactions.

23 (3) The pharmacy providing services to the facility pursuant to  
24 Section 4119.1 of the Business and Professions Code shall  
25 control access to the drugs stored in the automated drug delivery  
26 system.

27 (4) Access to the automated drug delivery system shall be  
28 controlled and tracked using an identification or password system  
29 or biosensor.

30 (5) The automated drug delivery system shall make a complete  
31 and accurate record of all transactions which will include all  
32 users accessing the system and all drugs added to or removed  
33 from the system.

34 (6) After the pharmacist reviews the prescriber's order, access  
35 by licensed personnel to the automated drug delivery system  
36 shall be limited only to the drug as ordered by the prescriber and  
37 reviewed by the pharmacist and that is specific to the patient.  
38 When the prescriber's order requires a dosage variation of the  
39 same drug, licensed personnel shall only have access to the drug  
40 ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

SEC. 2. Section 290.02 is added to the Penal Code, to read:

290.02. (a) Notwithstanding any other law, the Department of Justice shall ~~provide, upon written request, the names and relevant information pertaining to persons who are required to register pursuant to Section 290~~ *identify the names of persons*

1 *required to register pursuant to Section 290 from a list of*  
2 *persons provided by the requesting agency, and provide those*  
3 *names and other information necessary to verify proper*  
4 *identification,* to any state governmental entity responsible for  
5 authorizing or providing publicly funded prescription drugs or  
6 other therapies to treat erectile dysfunction of those persons.  
7 State governmental entities shall use information received  
8 pursuant to this section to protect public safety by preventing the  
9 use of prescription drugs or other therapies to treat erectile  
10 dysfunction by convicted sex offenders.

11 (b) Use or disclosure of the information disclosed pursuant to  
12 this section is prohibited for any purpose other than that  
13 authorized by this section or Section 14133.225 of the Welfare  
14 and Institutions Code. The Department of Justice may establish a  
15 fee for requests, including all actual and reasonable costs  
16 associated with the service.

17 (c) Notwithstanding any other provision of law, any state  
18 governmental entity that is responsible for authorizing or  
19 providing publicly funded prescription drugs or other therapies to  
20 treat erectile dysfunction may use the sex offender database  
21 authorized by Section 290.46 to protect public safety by  
22 preventing the use of those drugs or therapies for convicted sex  
23 offenders.

24 SEC. 3. Section 14133.225 is added to the Welfare and  
25 Institutions Code, to read:

26 14133.225. Notwithstanding any other law, the department  
27 shall not provide or pay for any prescription drug or other  
28 therapy to treat erectile dysfunction for any person who is  
29 required to register pursuant to Section 290 of the Penal Code,  
30 except to the extent required under federal law. The department  
31 may require from the Department of Justice the information  
32 necessary to implement this section.

33 SEC. 4. This act is an urgency statute necessary for the  
34 immediate preservation of the public peace, health, or safety  
35 within the meaning of Article IV of the Constitution and shall go  
36 into immediate effect. The facts constituting the necessity are:

37 In order to prevent funding of drugs or other therapies  
38 prescribed for erectile dysfunction for use by high-risk sex  
39 offenders and to make statutory changes related to automated

- 1 drug delivery systems, as soon as possible, it is necessary that
- 2 this act take effect immediately.

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